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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/171,081	12/14/1998	SASA KRANJC	22681-0002	7627

26633 7590 12/20/2004

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EXAMINER

PRATS, FRANCISCO CHANDLER

ART UNIT	PAPER NUMBER
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1651

DATE MAILED: 12/20/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

**Advisory Action**

Application No.

09/171,081

Applicant(s)

KRANJC ET AL.

Examiner

Francisco C. Prats

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--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 02 December 2004 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

**PERIOD FOR REPLY [check either a) or b)]**

- a) ☒ The period for reply expires 4 months from the mailing date of the final rejection.
- b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☐ A Notice of Appeal was filed on \_\_\_\_\_. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. ☒ The proposed amendment(s) will not be entered because:
- (a) ☒ they raise new issues that would require further consideration and/or search (see NOTE below);
  - (b) ☒ they raise the issue of new matter (see Note below);
  - (c) ☒ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
  - (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: See attachment.

3. ☐ Applicant's reply has overcome the following rejection(s): \_\_\_\_\_.
4. ☐ Newly proposed or amended claim(s) \_\_\_\_\_ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
5. ☒ The a) ☒ affidavit, b) ☒ exhibit, or c) ☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: See attachment.
6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.
7. ☒ For purposes of Appeal, the proposed amendment(s) a) ☒ will not be entered or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: \_\_\_\_\_.

Claim(s) objected to: \_\_\_\_\_.

Claim(s) rejected: 36,38,41-55 and 95.

Claim(s) withdrawn from consideration: \_\_\_\_\_.

8. ☐ The drawing correction filed on \_\_\_\_\_ is a) ☐ approved or b) ☐ disapproved by the Examiner.
9. ☐ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_.
10. ☐ Other: \_\_\_\_\_

Francisco C. Prats  
Primary Examiner  
Art Unit: 1651

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**ATTACHMENT TO ADVISORY ACTION**

The after-final amendment filed December 2, 2004, has been received. The Rule 132 Declaration of Sasa Kranjc has been received and considered. The text of those sections of Title 35, U.S. Code, not included in this action can be found in a prior office action.

The after-final amendment filed December 2, 2004, will not be entered because it raises new issues for search and consideration. The proposed claim amendment requires the consumption of all phosphate in the fermentation medium prior to a second addition of phosphate and maintenance of phosphate concentration. This is a new limitation which has not been searched or considered previously with respect to prior art and with respect to support in the specification. Because the new claim language requires additional search and/or consideration, non-entry of the proposed amendment is clearly proper under 37 CFR § 1.116.

All of applicant's argument has been fully considered but is not persuasive of error. Applicant's argument almost entirely assumes entry of the non-entered after-final amendment. While applicant states that the previous office action was non-final (page 5 of response of 12/2/04), the previous office clearly was a final rejection. In view of the non-entry of the

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amendment, the majority of applicant's argument is not directed claim limitations currently pending.

With respect to the allegation of unexpected results resulting from the use sodium dihydrogen phosphate in the fermentation medium, it is noted that unexpected results are not relevant to an analysis of rejections under § 102, said rejections still being pending by virtue of the non-entry of the amendment filed December 2, 2004. Moreover, of the actual pending claims, only claims 45 and 46 recite the use of sodium dihydrogen phosphate, with claim 45 still reciting the use of the potassium phosphate salts used in the Cole reference. Thus, applicant's argument in this respect is relevant only to claims 45 and 46, to the extent those claims recite sodium dihydrogen phosphate.

As to the significantly increased yield obtained from using the sodium salt instead of the Cole's potassium salt, it is noted that this increase came from a specific set of fermentative conditions which still are not recited in the claims, nor do the claims require any specific yield. While it is also noted that the increase in clavulanic acid production using the sodium salt over the potassium salt is not specific to a particular microbial strain, as evidenced by the Declaration by Sasa Krajc and the accompanying materials, the yield increase

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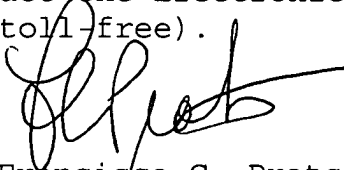
certainly is derived from a specific set of conditions not currently recited in the claims, particularly in view of the non-entry of the amendment of December 2, 2004. Moreover, to the extent the claims still encompass anticipatory prior art, any allegation of unexpected result is not relevant to the analysis of those claims.

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Francisco C. Prats whose telephone number is 571-272-0921. The examiner can normally be reached on Monday through Friday, with alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Francisco C. Prats  
Primary Examiner  
Art Unit 1651

FCP